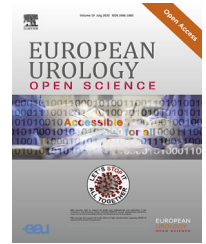


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Kidney Cancer

Initial Observation of a Large Proportion of Patients Presenting with Clinical Stage T1 Renal Masses: Results from the MUSIC-KIDNEY Statewide Collaborative

Amit K. Patel^a, Craig G. Rogers^a, Anna Johnson^b, Sabrina L. Noyes^c, Ji Qi^b, David Miller^b, Edward Shervish^d, Benjamin Stockton^e, Brian R. Lane^{c,f,*}, for the Michigan Urological Surgery Improvement Collaborative^b

^a Henry Ford Health System, Detroit, MI, USA; ^b Department of Urology, Michigan Medicine, Ann Arbor, MI, USA; ^c Spectrum Health Hospital System, Grand Rapids, MI, USA; ^d Michigan Institute of Urology, St. Clair Shores, MI, USA; ^e Lakeland Urology, St. Joseph, MI, USA; ^f Michigan State University College of Human Medicine, Grand Rapids, MI, USA

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Abstract

Background: While surgical excision remains the principal management strategy for clinical T1 renal masses (cT1RMs), the rates of noninterventional approaches are not well known. Most single-institution and population-based series suggest rates below 10%.

Objective: To evaluate the use of observation for newly diagnosed cT1RM patients in academic and community-based practices across a statewide collaborative.

Design, setting, and participants: The Michigan Urological Surgery Improvement Collaborative—Kidney mass: Identifying and Defining Necessary Evaluation and therapy (MUSIC-KIDNEY) commenced data collection in September 2017 by recording clinical, radiographic, pathologic, and short-term follow-up data for cT1RM patients at 13 diverse practices. Patients with complete data were assessed at >90 d after initial evaluation as to whether observation or treatment was performed.

Outcome measurements and statistical analysis: Relationships with outcomes were analyzed using multivariable logistic regression, chi-square test, and Wilcoxon rank-sum test.

Results and limitations: Out of 965 patients, observation was employed in 48% ($n = 459$), with practice-level rates ranging from 0% to 68%. Patients managed with observation (vs treatment) were significantly older (71.2 vs 62.8 yr, $p < 0.0001$) and had smaller tumors (2.3 vs 3.4 cm, $p < 0.0001$). Observation was used for 53.5% of cT1a renal masses, for 29.9% of cT1b renal masses, and for 42.5%, 53.7%, and 63.9% of radiographically solid, Bosniak III–IV cystic, and indeterminate cT1RMs, respectively. Factors significantly associated with observation in multivariable analysis included lesion type (Bosniak III–IV vs solid, $p = 0.017$), tumor stage (cT1a vs cT1b,

* Corresponding author. Betz Family Chair for Cancer Research, Spectrum Health Cancer Center, Urology Division, Spectrum Health Medical Group, 145 Michigan Street NE, Suite 5500, Grand Rapids, MI 49503, USA. Tel. +1-616-267-9333, Fax: +1-616-267-8040.
E-mail address: brian.lane@spectrumhealth.org (B.R. Lane).



$p < 0.001$), and higher age ($p < 0.001$). A short duration of follow-up limits the assessment of longer-term patient management.

Conclusions: Noninterventional management of cT1RMs is common across the MUSIC-KIDNEY collaborative, with wide variability across practices. Factors associated with observation were advanced age, smaller tumor size, and cystic tumor type. Durability of the initial decision for observation (delayed intervention vs active surveillance vs less active surveillance) will be a focus of subsequent study.

Patient summary: The Michigan Urological Surgery Improvement Collaborative: Kidney mass: Identifying and Defining Necessary Evaluation and therapy (MUSIC-KIDNEY) quality improvement collaborative assessed the current utilization of initial observation of a renal mass ≤ 7 cm across a diverse group of urology practices and found it to be used in 48% of patients. We found that the factors predicting observation were advanced age, smaller tumor size, and cystic tumor type.

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1. Introduction

The incidence of renal masses (RMs) has been on the increase over the last 2 decades [1–3], predominately due to the expanding utilization of cross-sectional abdominal imaging [4]. While surgical excision remains the principal management strategy, active surveillance (AS) has emerged as a safe alternative in well-selected patients. Both American Urological Association (AUA) and American Society of Clinical Oncology (ASCO) guidelines [5,6] include AS as a treatment option in the management of localized RMs up to 4 cm in size (clinical stage T1a or cT1a).

For clinical T1a renal masses (cT1aRMs), the risk of metastatic progression is low, with a meta-analysis determining the risk to be approximately 1% over a 32-mo period [7]. In addition, for all localized RMs, even those up to 7 cm in size (cT1), the risk of death from competing causes exceeds that of cancer-related death [8,9]. Retrospective series have indicated that surgical intervention for clinical T1 renal masses (cT1RMs) may provide no survival advantage in patients over the age of 75 yr, with patients more likely to die from competing cardiovascular and other noncancer comorbidities [10,11]. Patients who are comorbid or elderly may, therefore, be particularly suitable for AS. This is reflected in the rising trend of AS in patients over 70 yr of age, with the rate of AS increasing from 9.8% in 2002 to 13.6% in 2011 [12].

Understanding the current utilization of AS for cT1aRMs or cT1RMs is difficult, with an analysis of large national datasets such as the National Cancer Database (NCDB) and the Surveillance, Epidemiology and End Results (SEER)-Medicare database reporting AS utilization from 2.7% to 30% [13–16]. These may not reflect current management, given the limitations of under-reporting [17] and completeness with geographic, ethnic, and age variation and disease site [18].

The Michigan Urological Surgery Improvement Collaborative (MUSIC) initiated a prospective kidney mass registry for all patients with newly presenting cT1RMs. This study will aim to evaluate the initial management decision for cT1RMs across a diverse range of urology practices. We

hypothesized that the use of noninterventional approaches in academic and community-based practices for patients diagnosed with new cT1RMs is much higher than in most prior reports.

2. Patients and methods

2.1. MUSIC–Kidney mass: Identifying and Defining Necessary Evaluation and therapy

MUSIC–Kidney mass: Identifying and Defining Necessary Evaluation and therapy (MUSIC-KIDNEY) commenced data collection in September 2017 at eight diverse MUSIC practices, with 13 practices providing data through April 2019 [19]. Noyes et al [19] have previously reported on MUSIC-KIDNEY inception, data collection, and practice participation. The MUSIC coordinating center is responsible for overall administration and management of collaborative activities. One urologist per practice serves as the clinical champion with responsibilities that include oversight of local data collection and leadership around local implementation of quality improvement (QI) activities. Data abstractors recorded 122 data points at a single time point (120 d after initial consultation), with subsequent extraction at least 3 mo later to determine the final treatment assignment.

2.2. Study population

From September 2017 to April 2019, 1248 patients have currently been accrued who have presented to a MUSIC urologist for the first time with a cT1RM measuring ≤ 7 cm, as determined by imaging (computed tomography, magnetic resonance imaging, or ultrasound). The criteria for exclusion from analysis were Bosniak type I, II, and IIF cysts; clinical impression of angiomyolipoma (AML); nonsuspicious lesions; and incomplete data or follow-up (Fig. 1).

2.3. Patient characteristics

For each patient, the following variables were extracted: patient demographics—age, gender, Charlson Comorbidity Index (CCI), race (white vs black vs others), insurance category (private vs public [Medicare, Medicaid] vs uninsured vs unknown), estimated glomerular filtration rate (eGFR), and body mass index; physician characteristics—academic versus nonacademic, location (practices in southeast Michigan vs elsewhere), volume of cT1RMs evaluated, and utilization of renal mass

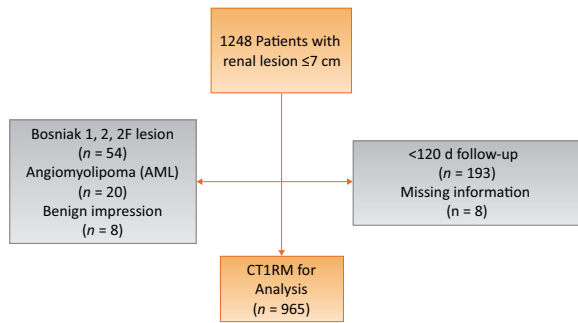


Fig. 1 – Consort diagram of patients included for analysis.

biopsy (RMB); tumor characteristics—size, nephrometry score (based on RENL characteristics of RENAL score stratified into low, intermediate, and high complexity), and characteristics (solid vs cystic [Bosniak III–IV] vs indeterminate, single vs multiple); and management at 120 d—treatment (partial nephrectomy, radical nephrectomy, thermal ablation, and other) versus observation (OB; no treatment received over study period). The terminology of “OB” has been used in this study (instead of AS) as the follow-up is limited to 120 d from initial consultation and includes patients who may eventually undergo delayed intervention, proceed to AS, or be followed with “less active” surveillance. AS was defined as a plan for reassessment with repeat imaging within 12 mo, less active surveillance as a plan to perform repeat imaging at >12 mo, reassurance as a plan to perform no other assessment of the RM, and deferred treatment as any intervention for cT1RMs performed after 90 d from initial clinical assessment.

2.4. Statistical analysis

Clinical and demographic characteristics of patients were summarized by the receipt of treatment using chi-square test for categorical variables and Wilcoxon rank-sum test for continuous measures. Practice-level variation in the utilization of OB among cT1RM patients was examined. A multivariable logistic regression model was used to identify factors associated with undergoing treatment (vs OB). All the analyses were performed using SAS 9.4, and statistical significance was indicated with $p < 0.05$.

3. Results

Among 965 patients, 506 (52%) underwent definitive treatment within 90 d of initial consultation and OB was employed in the remaining 459 patients (48%). Of the patients who received intervention, the treatment received was partial nephrectomy in 62% ($n = 314$), radical nephrectomy in 33% ($n = 165$), thermal ablation in 4.6% ($n = 23$), and other in 0.8% ($n = 4$). Patient, physician, and tumor characteristics for the OB and intervention cohorts are demonstrated in Table 1. The urologist indicated that the specific OB plan to be pursued was AS in 269 (59%), less active surveillance in 52 (11%), and reassurance in 10 (2.2%), and the plan was not detailed further in 128 (28%). Delayed intervention was observed in only 3.1% of OB patients (14 of 459) who had completed at least 6 mo since initial evaluation (median follow-up: 24.6 mo, interquartile range [IQR] 20.1–30.4 mo).

3.1. Patient characteristics

When compared with those who received intervention, patients receiving OB were older (71.2 vs 62.8 yr, $p < 0.001$). Age was a significant predictor of OB in both univariate and multivariable analysis (Table 2). Although there were associations of insurance (private 39.2%, public 55.7%, none 53.8%, $p < 0.001$), eGFR (<60 ml/min 51.3%, >60 ml/min 42.2%, $p = 0.014$), and coexisting nonrenal tumors (56.6% vs 45.7%, $p = 0.01$) with OB in univariable analysis, these associations were not maintained with multivariate analysis. CCI score and gender were not associated with the decision to observe or intervene for a cT1RM.

For 960 patients who could be classified as those aged <75 yr and with CCI < 2 versus those aged >75 yr or with CCI ≥ 2 , OB was utilized in 37.3% versus 59.5% ($p < 0.05$). For T1a tumors, OB for patients of age <75 yr and CCI < 2 versus those of age >75 yr or CCI ≥ 2 was 43.5% versus 65.8% ($p < 0.05$), and for T1b tumors, it was 19.7% versus 42.1% ($p < 0.05$).

3.2. Physician and practice characteristics

Practice-level utilization of OB ranged from 0% to 68%, with a median of 41.7% (IQR 6.4–50) across 13 MUSIC practices ($p < 0.001$; Fig. 2). Of note, seven sites contributed <20 patients each for analysis, with three of these practices observing 0%. Provider-level differences in utilization of OB were also noted, but the data are somewhat limited by the small number of evaluable patients for a provider-by-provider analysis (data not shown). On univariate analysis, physicians were more likely to observe a cT1RM if they practiced in a nonacademic setting (52.9% vs 42.8%, $p = 0.002$) and RMB was not performed (49.2% vs 39.5%, $p = 0.022$); however, these associations were not maintained on multivariate analysis. Practice location was also not associated with OB versus intervention on multivariable analysis.

3.3. Tumor characteristics

Tumors that were observed were smaller (median: 2.3 cm, IQR: 1.5–3.3 cm) than those undergoing treatment (3.4 cm, IQR: 2.4–4.6 cm, $p < 0.001$; Table 1). There was decreasing use of OB with each 1 cm increase: 77% of 0.1–1.0 cm, 66% of 1.1–2.0 cm, 49% of 2.1–3.0 cm, 34% of 3.1–4.0 cm, 33% of 4.1–5.0 cm, 27% of 5.1–6.0 cm, and 25% of 6.1–7.0 cm. OB was employed in 53.5% of cT1a tumors and 30% of cT1b tumors. Factors significantly associated with OB (vs intervention) in multivariable analysis were tumor size and radiographic tumor type (complex cystic 53.7%, indeterminate 63.9%, solid 42.5%, $p < 0.05$).

Nephrometry score was recorded for 49.3% of patients ($n = 473$). Increasing tumor complexity led to lower rates of OB (low 51.1%, intermediate 37.1%, high 34.9%, $p = 0.007$) in bivariate analysis. Tumor laterality (right 47%, left 47%, $p = 0.99$) and number of RMs (single lesion 47.4%, multiple lesions 46.3%, $p = 0.67$) were not predictors of OB. RMBs were performed in 17% of patients with cT1RMs. Benign or

Table 1 – Patient, physician, and tumor characteristics of observation versus treatment

	Patient management (n = 965)		Univariate p value
	Observation (n = 459)	Treatment (n = 506)	
Age (yr), median (IQR)	71.2 (61.1–78.7)	62.8 (53.3–71.0)	<0.001
Race/ethnicity, n (%)			
White	371 (47.9)	404 (52.1)	0.083
African American	62 (52.5)	56 (47.5)	
Others/unknown	26 (36.1)	46 (63.9)	
Gender, n (%)			
Male	248 (45.1)	302 (54.9)	0.077
Female	211 (50.8)	204 (49.2)	
Insurance type, n (%)			
Private	186 (39.2)	289 (60.8)	<0.001
Public	264 (55.7)	210 (44.3)	
None	7 (53.8)	6 (46.2)	
Physician practice, n (%)			
Academic	218 (42.8)	291 (57.2)	0.002
Nonacademic	241 (52.9)	215 (47.1)	
Location, n (%)			
Southeast Michigan	336 (46.5)	386 (53.5)	0.271
Elsewhere in Michigan	123 (50.6)	120 (49.4)	
BMI (kg/m ²)	29.4 (25.6–34.3)	29.6 (26.7–35.2)	0.048
Charlson comorbidity score, n (%)			
0	217 (44.1)	275 (55.9)	0.051
1	93 (48.2)	100 (51.8)	
>2	149 (53.2)	131 (46.8)	
GFR (n = 863), n (%) ^a			
>60	244 (42.2)	334 (57.8)	0.014
<60	136 (51.3)	129 (48.7)	
Size (cm), median (IQR)	2.3 (1.5–3.3)	3.4 (2.4–4.6)	<0.001
Tumor size/stage, n (%)			
T1a	379 (53.5)	330 (46.5)	<0.001
T1b	75 (29.9)	176 (70.1)	
Second malignancy (nonrenal), n (%)			
Yes	94 (56.6)	72 (43.4)	0.010
No	365 (45.7)	434 (54.3)	
Nephrometry score (n = 473), n (%) ^a			
Low	95 (51.1)	91 (48.9)	0.007
Intermediate	83 (37.1)	141 (62.9)	
High	22 (34.9)	41 (65.1)	
Multiple lesions, n (%)			
Single lesion	395 (47.4)	438 (52.6)	0.826
Multiple lesions	50 (46.3)	58 (53.7)	
Radiographic lesion type, n (%)			
Solid	301 (42.5)	408 (57.5)	<0.001
Complex cyst (Bosniak III & IV)	29 (53.7)	25 (46.3)	
Indeterminate	129 (63.9)	73 (36.1)	
Renal biopsy performed, n (%)			
Yes	66 (39.5)	101 (60.5)	0.022
No	393 (49.2)	405 (50.8)	

BMI = body mass index; GFR = glomerular filtration rate; IQR = interquartile range.

^a Number of patients with information available for analysis for this domain.

favorable benign diagnoses were made in 21% of these patients. Of patients without malignancy at RMB, 86% were placed on OB.

4. Discussion

Acceptance of AS as a treatment strategy for small RMs is growing [13]. This is, in part, based on the long-term oncologic outcomes seen in a growing number of single-institutional series and evidence indicating the safety of AS up to 10 yr in duration in select centers [7,20,21]. Rates of AS have been reported to be in the range of 2.9–30% in prior population-based studies [13,15,16,22], which are signifi-

cantly lower than the 46% AS rate demonstrated in this study. We observed significant variability in the use of OB (rates: 0–68%) within the 13 practices participating in MUSIC-KIDNEY. Only one prior group of three academic sites, the Delayed Intervention and Surveillance for Small Renal Masses Registry (DISSRM), has reported a similar rate (45%) of AS [20].

How can this discrepancy be understood? Several factors deserve consideration: first, there is no clearly specified definition or pathway for AS of cT1aRMs. In addition, many patients with cT1aRMs do not need AS, as they are initially provided reassurance that the lesion in question is not suspicious for cancer. These patients might be better

Table 2 – Multivariable logistical regression analysis to identify factors associated with undergoing treatment versus observation

Effect	OR	95% CI		p value
		Lower limit	Upper limit	
Age	0.95	0.94	0.96	<0.0001
BMI	0.99	0.97	1.01	0.350
Female (vs male)	0.84	0.62	1.12	0.227
Race				
African American (vs white)	0.78	0.49	1.23	0.278
Other/unknown (vs white)	1.07	0.60	1.91	0.808
Insurance				
Private (vs none)	2.32	0.70	7.63	0.168
Public (vs none)	2.05	0.62	6.82	0.240
Charlson comorbidity index				
1 (vs 0)	1.07	0.73	1.57	0.726
≥2 (vs 0)	0.89	0.56	1.44	0.644
Other malignancy	0.79	0.45	1.37	0.392
Clinical stage T1b (vs T1a)	2.90	2.06	4.07	<0.0001
Radiographic tumor type				
Complex cyst (vs solid)	0.47	0.25	0.88	0.017
Complex cyst (vs indeterminate)	0.98	0.49	1.94	0.946
Renal mass biopsy	1.36	0.93	2.00	0.112
Multiple lesions (vs single lesion)	0.97	0.61	1.54	0.908
Academic practice (vs private)	1.27	0.87	1.86	0.219
Southeast Michigan (vs elsewhere)	1.11	0.72	1.71	0.645

BMI = body mass index; CI = confidence interval; OR = odds ratio.

Tumor complexity was not included as a variable due to incomplete information of 489 patients.

assigned a term such as “reassurance” or “OB,” which is more aligned with the clinical intent to observe a benign lesion, than the term “watchful waiting” in which the clinical impression is that the patient will not benefit from localized treatment for the presumed cancer [23]. Other lesions that are indeterminate or are too small to characterize are also commonly observed but would not appear in cancer registries. For these reasons, the actual rates of OB (vs AS) may differ dramatically. Applying the criteria used to identify patients in the SEER/Medicare registry to our series of patients, only 4.4% of patients would be found to be on AS. Similarly, for the NCDB, the proportion on AS would be 6.8%. Our methodology, therefore, allows for an explanation of these seemingly disparate results.

Our data are not the first to indicate a high rate of OB for small RMs. Pierorazio et al [20] in 2015 reported the results of the DISSRM registry, where 45% of patients underwent AS after initial presentation. They had postulated that their higher observed rates of AS were attributed to (1) patients being seen in tertiary referral centers where patients with complex presentations are evaluated; (2) an inherent propensity to select AS (for patients and physicians alike) when a surveillance protocol exists; and (3) a small proportion of patients undergoing primary intervention either refusing or missing enrollment, while very few patients choosing AS refusing enrollment to DISSRM. A recent presentation by Menon et al [24] described the use of “universal” surveillance for RMs as well, where failure to remain on protocol was seen only in 1% of patients.

Our data provide further insights into noninterventional strategies for cT1RMs, suggesting alternative explanations for the high rates of noninterventional approaches observed in 13 practices contributing data to MUSIC-KIDNEY. First, it does not appear that OB rates were high only at tertiary

referral centers, as almost half of the patients within the MUSIC-KIDNEY collaborative were managed at community practices. Second, no MUSIC-led protocol for the management of T1RMs exists at present, and there has not yet been a QI effort targeting increased (or decreased) use of OB in Michigan. Third, within MUSIC-KIDNEY, there is no concern about selection bias for enrollment, as all patients with cT1RMs at participating sites are included. Additionally, the MUSIC registry includes all cT1RMs (both cT1a and cT1b), while most of the previous studies examined only cT1a tumors, making our findings even more striking. In our study, OB was employed in 53.5% of patients with cT1a tumors and 30% of patients with cT1b tumors. It is possible that the inclusion of all RMs presenting to a MUSIC-KIDNEY urologist might have allowed for more nonsuspicious lesions to be included in our dataset. We, however, excluded simple and minimally complex cysts (Bosniak I, II, IIF), AMLs, and clinician-determined nonsuspicious lesions at the outset. Indeterminate lesions were included, and these patients were more likely to undergo OB (63.9%) than those with Bosniak III–IV cysts (53.7%) or solid tumors (42.5%); however, when the indeterminate lesions are excluded, OB was still employed in 43% of all suspicious cT1 lesions. The higher rate of OB seen in case of suspicious complex cysts is not surprising. It has been shown that they exhibit low cancer mortality risk [25] and 50% likelihood of a Bosniak III cyst having benign pathology outcome at surgical intervention [26].

There are several notable findings from our analysis regarding the utilization of OB within our collaborative. The patient factor most strongly associated with OB was older age, as has been shown in several other studies [14,15]. Of note, there was no association between medical comorbidity or baseline renal function and choice of OB, despite prior

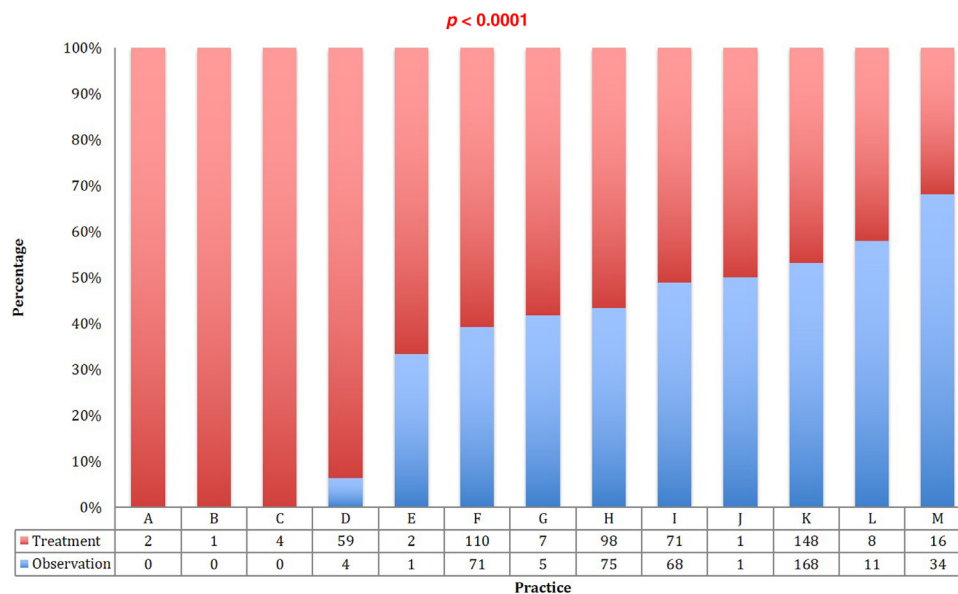


Fig. 2 – Practice variation of observation of cT1RM. The box table demonstrates the number of patients at each practice undergoing observation versus treatment. cT1RM=clinical T1 renal mass.

reports indicating that those with comorbid illnesses have competing mortality risks [9,11]. This might discriminate itself with longer follow-up, where more comorbid patients adopt a “watchful waiting” strategy and younger, healthier patients adopt AS with some proportion undergoing delayed intervention. This hypothesis will be tested when greater length of follow-up is available in the MUSIC-KIDNEY cohort.

Variability was seen in the utilization of OB among practices; however, no obvious factors seemed to attribute to this variability. A prior NCDB study [15] had reported academic setting being a factor in increased OB; however, this was not seen in our study, with no difference observed on multivariate analysis. Owing to a small number of cases (<20) in seven practices, further analysis per practice could not be performed at this time. After OB has been selected initially, each patient is managed with AS, “less active” surveillance, or reassurance. These differ in terms of approach/intent and protocol. Examining variation in the selection of each of these approaches, and standardizing these approaches, will be a QI goal for the collaborative in the near term. RMB was performed in only 14% of patients undergoing OB. At present, the AUA identifies RMB as an option for the newly presenting RMs [5]. The European Association of Urology (EAU) recommends RMB in patients in whom OB is pursued (grade C evidence) [27]. While there has been increasing zest for RMB in the urologic literature and a number of centers around the world are recommending RMB [28], this does not hold true in our collaborative. The DISSRM registry was also criticized for a low RMB rate, but we would argue that more RMBs do not necessarily lead to less intervention overall, particularly when performed on patients inclined toward OB. In MUSIC-KIDNEY practices, the likelihood of intervention was almost 9% higher in patients undergoing RMB than in those in whom

had been performed, contrary to prior reports [29]. This might be a result of patients receiving a certain diagnosis of malignancy at RMB, leading to the patient and/or loved ones feeling a greater urgency for intervention. Further investigation of the factors leading to RMB and its utilization will be the focus of further studies.

The most notable limitation of the present study is the short follow-up. The patients within this cohort classified as being managed initially with OB will be categorized, with longer follow-up, into four groups: reassurance (for nonmalignant lesions), watchful waiting (or less active surveillance), AS, and delayed intervention. The DISSRM registry has reported that crossover to delayed intervention was limited to 9% [20]. The MUSIC-KIDNEY registry continues to collect data on all patients at least yearly after enrollment, allowing for the opportunity to further assess outcomes with time. It is also important to recognize that this study had seven practices, with each contributing <20 patients. As a result, some patterns observed may be biased by the higher-volume centers.

5. Conclusions

The MUSIC-KIDNEY statewide QI collaborative provides an opportunity to assess the factors that influence the management of cT1RMs across a range of practice types. OB is employed widely across our state, with 48% of renal tumors ≤ 7 cm being managed initially without definitive intervention. OB is more common for tumors <3 cm, age >75 yr, and indeterminate renal lesions, but is also performed selectively in those not meeting these criteria.

Author contributions: Brian R. Lane had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Lane, Patel, Rogers.

Acquisition of data: Johnson, Noyes, MUSIC.

Analysis and interpretation of data: Lane, Patel, Rogers, Qi.

Drafting of the manuscript: Patel, Lane.

Critical revision of the manuscript for important intellectual content: Shervish, Stockton, Qi, Johnson, Noyes.

Statistical analysis: Qi.

Obtaining funding: MUSIC, Lane.

Administrative, technical, or material support: Johnson, Noyes.

Supervision: Lane, Rogers, Miller.

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